UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

JEREMY OLSEN,

Plaintiff,

v.

NORRIS W. COCHRAN,[1] in his official capacity as the acting Secretary of the United States Department of Health and Human Services,

Defendant.

No. 2:20-cv-00374-SMJ

ORDER GRANTING PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND DENYING DEFENDANT'S CROSS MOTION FOR SUMMARY JUDGMENT

Before the Court, without oral argument, are Plaintiff's Motion for Summary Judgment, ECF No. 22, and Defendant's Cross Motion for Summary Judgment, ECF No. 27. The Court has reviewed the record and pleadings in this matter, is fully informed, and grants summary judgment for Plaintiff.

BACKGROUND

Plaintiff Jeremy Olsen alleges he is a 41-year-old Type I diabetic who has suffered kidney failure and undergone a kidney transplant due to his condition. ECF

[1] Norris W. Cochran has succeeded Alex M. Azar, II, as acting United States Secretary of Health and Human Services.

No. 1 at 10. Plaintiff uses a Medtronic MiniMed Continuous Glucose Monitor ("CGM)", which he alleges a doctor prescribed to help avoid failure of his transplanted kidney and prevent other complications from his diabetes. *Id.* at 11. Plaintiff suffers from hypoglycemic unawareness, meaning he cannot tell when his blood sugar is low. *See* AR 041.

After his claim for Medicare coverage of the CGM supplies was initially denied as not "durable medical equipment," an Administrative Law Judge eventually approved Plaintiff's claim. *Id.* at 11–12. But the Medicare Appeals Council/Departmental Review Board ("Appeals Council") reversed the ALJ, determining that a CGM is not "durable medical equipment" because it is not "primarily and customarily used to serve a medical purpose." *Id.* at 12.

Plaintiff sought judicial review in the U.S. District Court for the District of Columbia. ECF No. 1. The case was transferred to this Court. ECF No. 14. Plaintiff alleges six causes of action. ECF No. 1. Among other things, he claims the Appeals Council based its decision on CMS-1682-R, a "final opinion and order" regarding CGM coverage, which the Department of Health and Human Services issued without a public notice and comment period. *Id.* at 8. He also argues substantial evidence did not support the Appeals Council's decision to deny coverage and its decision was arbitrary and capricious. *Id.* at 15.

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LEGAL STANDARD

Courts must "grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A fact is "material" if it could affect the suit's outcome under the governing law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). An issue is "genuine" if a reasonable jury could find for the nonmoving party based on the undisputed evidence. *Id.* The moving party bears the "burden of establishing the nonexistence of a 'genuine issue.'" *Celotex Corp. v. Catrett*, 477 U.S. 317, 330 (1986). "This burden has two distinct components: an initial burden of production, which shifts to the nonmoving party if satisfied by the moving party; and an ultimate burden of persuasion, which always remains on the moving party." *Id.* Still, when a case involves reviewing a final agency determination under the APA, courts generally need not perform any fact-finding. *Nw. Motorcycle Ass'n v. United States Dep't of Agric.*, 18 F.3d 1468, 1471–72 (9th Cir. 1994). As this Court must confine the scope of its review to the administrative record, it finds this case ripe for resolution by summary judgment.

This Court reviews the Appeals Council's decision under the APA. *All. for the Wild Rockies v. Bradford*, 856 F.3d 1238, 1242 (9th Cir. 2017); *see also* 5 U.S.C. §§ 701, 704. This Court will set aside a final agency action if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5

U.S.C. § 706(2)(A); *see also Oregon Nat. Desert Ass'n v. U.S. Forest Serv.*, 957 F.3d 1024, 1032 (9th Cir. 2020).

"Review under the arbitrary and capricious standard is narrow, and [the court does] not substitute [its] judgment for that of the agency." *Oregon Nat. Desert*, 957 F.3d at 1032 (9th Cir. 2020) (alteration added) (citation and quotation marks omitted). Courts will find

> an agency action as arbitrary and capricious 'if the agency [1] has relied on factors which Congress has not intended it to consider, [2] entirely failed to consider an important aspect of the problem, [3] offered an explanation for its decision that runs counter to the evidence before the agency, or [4] [if the agency's decision] is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Id. at 1033 (numbering added) (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). Still, "[a]n agency decision will be upheld as long as there is a rational connection between the facts found and the conclusions made." *Barnes v. U.S. Dep't of Transp.*, 655 F.3d 1124, 1132 (9th Cir. 2011). "[A]s a practical matter, the arbitrary and capricious standard incorporates the substantial evidence test." *ASSE Int'l, Inc. v. Kerry*, 803 F.3d 1059, 1072 (9th Cir. 2015) (internal quotation omitted). "Substantial evidence means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Id.* (internal alterations omitted).

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DISCUSSION

Plaintiff focuses in his motion on his argument that CMS 1682-R improperly issued without proper notice and comment. *See* ECF No. 22. But he addresses the substantive considerations in his response to Defendant's motion. *See* ECF No. 32 at 11. Because there are no issues of material fact in this appeal of an agency decision and both parties have had notice and an opportunity to address all issues, the Court may rule for Plaintiff on substantive grounds. *See* Fed. R. Civ. P. 56(f); *see also* ECF No. 27. Because the Court determines that the Appeals Council erred in its determination that the CGM does not constitute durable medical equipment, it need not address Plaintiff's procedural arguments.

A. This Court agrees with other district courts which have determined that the CGM constitutes durable medical equipment

Medicare Part B generally covers, among other things, "medical and other health care services." 42 U.S.C. § 1395k(a)(2)(B). "Medical and other health services" includes "durable medical equipment." *Id.* § 1395x(s)(6). The statute defines durable medical equipment by listing certain equipment that qualifies—including "blood-testing strips and blood glucose monitors for individuals with diabetes without regard to whether the individual has Type I or Type II diabetes or to the individual's use of insulin (as determined under standards established by the Secretary in consultation with the appropriate organizations)"—and certain

equipment that does not. *Id.* § 1395x(n). The Secretary maintains that CGM monitors measure interstitial fluid, rather than blood-glucose levels, and so is not *enumerated* in the statutory definition of durable medical equipment. *See* AR 014; *see also* ECF No. 27 at 6.

But the Court need not decide that issue. Section 1395x(n) is not exhaustive. For unenumerated items, the regulations require that "durable medical equipment" meets five requirements: (1) "[c]an withstand repeated use"; (2) "has an expected life of at least 3 years"; (3) "[i]s primarily and customarily used to serve a medical purpose"; (4) "[g]enerally is not useful to an individual in the absence of an illness or injury"; and (5) "[i]s appropriate for use in the home." 42 C.F.R. § 414.202.

Relying on CMS-1682-R, the Appeals Council determined that "CGMs that are approved by the FDA for use as adjunctive devices to complement, not replace, information obtained from blood glucose monitors in making diabetes treatment decisions are referred to as 'non-therapeutic' CGMs" and so are not considered durable medical equipment." AR 013–14 (quoting CMS-1682-R at 7). It then noted that "classifying a device as DME (or not DME) has to do with its primary function in medical treatment, not any individual's use of the device." AR 018.

The regulation, as noted, defines "durable medical equipment" as equipment that, along with other requirements, is "primarily and customarily used to serve a medical purpose." *See* 42 C.F.R. § 414.202. Equipment is not durable medical

equipment just because "it may have some remote medically related use." AR 019 (internal quotation omitted). People commonly understand the adjective "medical" to mean relating to the practice of medicine, and "medicine," in turn, means "the science and art of preventing, curing, and alleviating sickness or affliction." *See* Black's Law Dictionary 1131 (10th ed. 2014); *see also Yith v. Nielsen*, 881 F.3d 1155, 1165 (9th Cir. 2018) (holding, for purposes of statutory interpretation, "[w]hen determining the plain meaning of language, [courts] may consult dictionary definitions") (internal quotation and citation omitted); *Zieroth v. Azar*, No. 20-cv-00172-MMC, 2020 WL 5642614, at *6 (N.D. Cal. Sept. 22, 2020). In short, the regulation "is clear on its face." *See Whitcomb v. Hargan*, 2:17-CV-00014, 2017 U.S. Dist. LEXIS 216571, at *13 (E.D. Wisc. Oct. 26, 2017).

When a regulation is ambiguous, the promulgating agency's interpretation is entitled to deference "unless it is plainly erroneous or inconsistent with the regulation." *See Kisor v. Wilkie*, 139 S. Ct. 2400, 2411 (2019) (internal quotation and citation omitted). But a district court need not defer to the agency's interpretation when, as here, the regulation is not "genuinely ambiguous." *See id.* at 2415. Even if 42 C.F.R. § 414.202 could be characterized as "genuinely ambiguous," as set forth below, the interpretation provided in CMS-1682-R is not reasonable. *See Zieroth*, 2020 WL 5642614, at *3.

No evidence supports the Appeals Council's conclusion that a CGM is not "primarily and customarily used to serve a medical purpose." There is nothing in the phrase "primarily and customarily used to serve a medical purpose," that requires covered devices to serve a "primary" medical purpose, rather than an "adjunctive" medical purpose." *Cf.* AR 013–14 (quoting CMS-1682-R at 7); AR 018; *see also Zieroth*, 2020 WL 5642614, at *4. This interpretation does not render the requirement that a device "generally is not useful to an individual in the absence of an illness or injury" superfluous. *Cf.* AR 020. True, Plaintiff must still use a blood glucose monitor. *See* AR 107. Even so, his CGM serves a distinct primary medical purpose, as it "offer[s] him greater glycemic control." AR 117. His CGM is particularly important because of his kidney transplant and hypoglycemic unawareness. AR 117–18. As the Court understands it, the blood glucose monitor is effective but only provides a reading for a specific moment in time. The CGM, on the other hand, gives more frequent readings but must be occasionally calibrated with the blood glucose monitor. *See* AR 030; ECF No. 1 at 5. Diabetics like Plaintiff (with hypoglycemic unawareness) may not realize that their blood sugar has dropped to dangerous levels, and the CGM helps prevent adverse health consequences by alerting Plaintiff of such changes. *See* AR 030; ECF No. 32 at 2.

"A technology's purpose is not altered just because it must be calibrated or confirmed by another technology. The primary and customary purpose of a

mechanical clock is to tell time, and that purpose is the same regardless of the fact that the clock might occasionally need to be calibrated with reference to a more accurate clock." *Bloom v. Azar*, No. 5:16-cv-121, 2018 WL 583111, at *10 (D. Vt. Jan. 29, 2018), *reversed on other grounds by* 976 F.3d 157 (2d. Cir. 2020).

Thus, the Court joins the district courts who have found that the CGM constitutes durable medical equipment. *See Zieroth*, 2020 WL 5642614 at *4; *Whitcomb*, 2017 U.S. Dist. LEXIS 216571 at *15 (noting, if Secretary "did not intend to provide coverage for secondary medical equipment, then the regulatory definition . . . must be revised to reflect that ideal"); *Bloom*, 2018 WL 583111, at *10 (holding requirement that device be "primarily and customarily used to serve a medical purpose" has "nothing to do with whether the equipment is the 'primary' equipment used to serve that purpose"); *Lewis v. Azar*, 308 F. Supp. 3d 574, 579 (D. Mass. 2018) (rejecting Secretary's argument that "a device loses its medical nature if it is used in conjunction with another medical device"). The Court finds the Secretary's interpretation of 42 C.F.R. § 414.202, even if such regulation were deemed genuinely ambiguous, is unreasonable and thus not entitled to deference. *See Kisor*, 139 S. Ct. at 2415-16 (holding, to be entitled to deference, interpretation must be "within the bounds of reasonable interpretation"). The Medtronic MiniMed Continuous Glucose Monitor is "primarily and customarily used to serve a medical purpose," and there is no apparent dispute that the other four requirements in 42

C.F.R. § 414.202 are satisfied. The Appeal's Council thus erred in denying Plaintiff's coverage.

Accordingly, **IT IS HEREBY ORDERED**:

1. Plaintiff's Motion for Summary Judgment, **ECF No. 22**, is **GRANTED**.

2. Defendant's Cross Motion for Summary Judgment, **ECF No. 27**, is **DENIED**.

3. This decision of the Appeals Council is **REVERSED**. This case is **REMANDED** with instructions to authorize coverage consistent with this Order.

4. Norris W. Cochran has succeeded Alex M. Azar, II, as Acting United States Secretary of Health and Human Services. Accordingly, this Court **SUBSTITUTES** Norris W. Cochran for Alex M. Azar, II, as a Defendant in this matter under Fed. R. Civ. P. 25(d). The Clerk's Office is directed to **AMEND** the caption accordingly.

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5. The Clerk's Office is directed to **CLOSE** the file.

IT IS SO ORDERED. The Clerk's Office is directed to enter this Order and provide copies to all counsel.

DATED this 23rd day of February 2021.

SALVADOR MENDOZA, JR.
United States District Judge